510(k) Summary of Safety and Effectiveness

AUG 2 8 2012

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

1) Submitter's name, address, telephone number, contact person
Submitted by:

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Corresponding Official:

Jacques Souquet
Chief Executive Officer
Telephone: 011 33 442 99 24 35

Date: August 24, 2012

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic Ultrasound System with Accessories
Proprietary Name: Aixplorer®

Classification:

Regulatory Class: II

Classification Name:	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Devices
AIXPLORER® Ultrasound Imaging System (K091970), cleared August 12, 2009
AIXPLORER® Ultrasound Imaging System (K102041), cleared October 18, 2010

4) Description of Device

The SuperSonic Imagine AIXPLORER® system is a cart based ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging studies. The system contains a scan converter and can be coupled to a variety of linear, curved, micro-convex, and motorized linear array transducers to produce images that are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles. The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode, Color Flow, Pulsed Wave Doppler, Harmonic Imaging, Amplitude Doppler, 3D imaging and for ShearWave™ elastography.

5) Intended Use

The SuperSonic Imagine AIXPLORER® ultrasound system and transducer are intended for general purpose pulse echo ultrasound imaging and Doppler fluid flow analysis of the human body.

6) Indication for Use

The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal).

7) Safety Considerations

As a Track 3 ultrasound device, the SuperSonic Imagine AIXPLORER® ultrasound system is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment" AIUM/NEMA 2004a published by the National Electrical Manufacturers Association as UD -3. With respect to limits on acoustic outputs, the SuperSonic Imagine AIXPLORER® ultrasound system complies with the FDA guideline limits set in the September 9, 2008, 510(k) diagnostic ultrasound guidance.

With regard to general safety, the SuperSonic Imagine AIXPLORER® ultrasound system scanner is designed to comply with IEC 60101 -1 (2005) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, and IEC 60601 - 2-37 (2007): Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The device's acoustic output limits are:

Mechanical Index	1.9 (Maximum)
TIS/TIB	0.1 – 4.0 (Range)
ISPTA (d)	720 mW/cm2
ISPPA (d)	0 – 700 W/cm2

The limits are the same as predicate Track 3 devices. These considerations apply to all modes the system offers.

8) Comparison to Predicate Devices

The SuperSonic Imagine AIXPLORER® system and transducers are identical to the predicate devices with regard to intended use, imaging capabilities, safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The systems have the same clinical indications for use.
- The systems have the same B-Mode (grayscale imaging) and Doppler capabilities.
- The systems have similar capability in terms of harmonic imaging, spatial compound imaging, elastography imaging and other image post-processing features to improve the image quality and aid in clinical evaluation and diagnosis.
- The transducers are identical in materials, manufacture and clinical capability.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The systems have identical capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The systems have been found to be manufactured in compliance with approved electrical and physical safety standards.

The SuperSonic Imagine AIXPLORER® system and transducers are identical to the predicate device identified in K102041; only the display of the device is changed in the elastography mode. A graduated and adjustable numeric scale, with units in m/s, will be added next to the color bar, so that users will be able to change the dynamic range displayed and return repeatedly and consistently to the selected range for the particular patient examination.

9) Nonclinical Performance Data

The SuperSonic Imagine AIXPLORER® system and transducers are identical to the predicate device identified in K102041; only the display of the device is changed in the elastography mode. Therefore no additional non clinical performance data was submitted for determination of substantial equivalence.

The following non clinical performance tests were conducted to demonstrate the performance of the device in the elastography mode.

9.1 Bias and Precision of Shearwave Velocity Estimation

This test was conducted using a CIRS 049A Quality Assurance elasticity phantom. This phantom contains stepped-cylinder targets of four stiffness types I – IV corresponding to nominal shear wave speeds of 1.6, 2.2, 3.9 and 5.2 m/s of different diameters, embedded in uniform-elasticity background (nominal shear wave speeds of 2.9 m/s).

Shearwave velocity estimation bias was derived as the difference between the mean of five independent shear wave velocity measurements and the nominal shear wave velocity, normalized by the nominal shear wave velocity and expressed as a percentage.

Shearwave velocity estimation precision was derived as the standard deviation of five independent shear wave velocity measurements normalized by the mean of the five independent measurements, and expressed as a percentage.

The tables below document the estimation bias and estimation precision as a function of target size and target stiffness for all transducers where the Elastography mode is available.

SLV16-5								
	TargetType: I		TargetType: II		TargetType: III		TargetType: IV	
Target Diameter (mm)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)
4.1	21.9	3.9	-7.0	2.2	-19.2	2.3	-24.1	1.9
6.5	7.6	0.2	-7.8	2.2	-8.7	1.3	-12.5	2.2
10.4	6.4	2.2	-8.6	1.8	-3.2	1.3	3.7	0.9
16.7	1.6	0.2	-8.6	1.8	-0.2	1.0	9.5	0.9

SL15-4								
	TargetType: I		TargetType: II		TargetType: III		TargetType: IV	
Target Diameter (mm)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)
4.1	19.5	0.2	-5.3	0.3	-16.2	2.4	-24.5	2.3
6.5	7.6	0.2	-7.8	2.2	-9.7	0.4	-12.5	0.9
10.4	1.6	0.2	-9.4	0.3	-3.7	1.3	-0.9	1.5
16.7	1.6	0.2	-8.6	1.8	5.3	0.4	8.8	1.3

SL10-2								
	TargetType: I		TargetType: II		TargetType: III		TargetType: IV	
Target Diameter (mm)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)
4.1	25.5	0.2	-4.5	1.7	-21.8	1.3	-22.2	1.0
6.5	13.5	0.2	-5.3	0.3	-10.2	1.1	-9.8	1.7
10.4	7.6	0.2	-5.3	0.3	-0.2	1.0	-0.1	2.0
16.7	1.6	0.2	-5.3	0.3	6.3	1.2	7.2	0.9

SE12-3								
	TargetType: I		TargetType: II		TargetType: III		TargetType: IV	
Target Diameter (mm)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)
6.5	26.7	1.9	-2.8	2.1	-13.7	1.4	-17.9	1.9
10.4	7.6	0.2	-6.1	1.8	-5.7	1.3	-0.9	0.8
16.7	1.6	0.2	-5.3	0.3	1.3	1.2	9.9	0.7

SC6-1								
	TargetType: I		TargetType: II		TargetType: III		TargetType: IV	
Target Diameter (mm)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)	BIAS (%)	PRECISION (%)
6.5	43.4	0.2	2.1	1.6	-27.3	0.4	-39.6	1.3
10.4	21.9	2.4	-2.0	1.7	-14.2	1.2	-22.2	1.0
16.7	5.2	2.8	-7.0	2.2	-7.2	0.0	-11.0	3.4

The results of this test demonstrate that the shearwave velocity estimates exhibit high precision for all target types and sizes considered, and are accurate with target sizes compatible to a transducer's elastography spatial resolution.

9.2 Depth Dependence of Elastography Velocity Estimation

The Depth Dependence Test was conducted using the same CIRS049A phantom as in the Bias and Precision Test described above.

Shearwave velocity estimates were obtained through the uniform-elasticity background material of the CIRS 049A phantom at multiple depths up to the penetration depth of each transducer. Five independent measurements were performed per depth and were used to calculate the shearwave velocity average and standard deviation values per depth.

The table below provides the results of this test:

	SLV15-6	SL15-4	SL10-2	SE12-3	SC6-1

DEPTH (mm)	SWV AVG (m/s)	SWV STD (m/s)	SWV STD (m/s)	SWV STD (m/s)	SWV AVG (m/s)	SWV STD (m/s)	SWV AVG (m/s)	SWV STD (m/s)	SWV AVG (m/s)	SWV STD (m/s)
5	2.86	0.05	2.78	0.04	2.80	0.01	2.90	0.01		
10	2.80	0.01	2.80	0.01	2.72	0.04	2.80	0.01		
15	2.70	0.01	2.68	0.04	2.70	0.01	2.70	0.01		
20	2.72	0.04	2.70	0.01	2.70	0.01	2.68	0.01		
25	2.70	0.01	2.70	0.01	2.68	0.04	2.64	0.05		
30					2.70	0.01			2.90	0.01
35					2.70	0.01			NA	NA
40					2.80	0.01			2.70	0.01
50									2.70	0.01
60									2.60	0.01
70									2.60	0.01

The results of this test demonstrate that the shearwave velocity estimates exhibit satisfactory agreement for all transducers and depths considered.

10) Conclusion

The documentation provided demonstrates that:

1) The system and transducers are substantially equivalent to the predicate devices.
2) There are no new questions of safety and effectiveness concerning the SuperSonic Imagine AIXPLORER® ultrasound system and transducers.
3) The ultrasound device has been scientifically evaluated and demonstrated to be as safe and effective as the predicate devices identified in item 3.
   The system's acoustic power levels are below the applicable FDA limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 2 8 2012

Mr. Jacques Souquet
Chief Executive Officer
SuperSonic Image, S.A.
Les Jardins de la Duranne – Bat. E & F
510, rue Rene Descartes
AIX-EN-PROVENCE CEDEX 13857
FRANCE

Re: K112255
Trade/Device Name: AIXPLORER® Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 26, 2012
Received: June 26, 2012

Dear Mr. Souquet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AIXPLORER® Ultrasound System, as described in your premarket notification:

Transducer Model Number

SL 15-4 (1D linear array)
SC6-1 (curved array)
SE 12-3 (endocavitary)
SLV16-5 (motorized linear)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Brendan O'Leary at (301) 796-6898.

Sincerely Yours,

for

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use

510(k) number (if known):
Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Indications for Use:
The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal).

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k K112255

Diagnostic Ultrasound Indications for Use

510(k) number (if known):
Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal (including urolology)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Trans-vaginal	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Intravascular							
	GYN	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Pelvic	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
Vessel	Other (Specify)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7

P = previously cleared by FDA (K102041)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography

(Division Sign-Off)
Division of Radiological Devices
510k K112255 OIVD

3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies
8: 3D Imaging

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K112255

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SL15-4 transducer (1D Linear Array Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3	P 4, 5, 6, 7
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
Vessel	Other (Specify)							

P = previously cleared by FDA (K102041)
Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies

(Division Sign-Off)
Division of Radiological Devices
510k K112255 OIVD

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Michael D O'Hara

K112255

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SC6-1 transducer (curved array transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal (including urolology)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Intravascular							
	GYN	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Pelvic	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
Vessel	Other (Specify)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7

P = previously cleared by FDA (K102041)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Radiological Devices
510k K112255 DIVD

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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K112255

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SE12-3 transducer (endocavitary transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Trans-vaginal	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Pelvic	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7

P = previously cleared by FDA (K102041)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave

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Division of Radiological Devices
OIVD

510k K112255

4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K112255

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SLV16-5 transducer (motorized linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 2, 3	P, 4, 5, 6, 7, 8
Vessel	Other (Specify)							

P = previously cleared by FDA (K102041)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave

(Division Sign-Off)
Division of Radiological Devices

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4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies
8: 3D imaging

Prescription Use __XX_____ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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